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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,339	06/16/2005	Celia Palacin	0690-0124PUS1	7354

2292 7590 04/17/2008
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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
04/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/539,339	PALACIN ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Sheets (2)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-27 are pending in the application.

Applicant's election with traverse to group I in the reply filed on 02/13/08 is acknowledged. The traversal is on the ground(s) that group III is an allowable given that the elected invention. This is not found persuasive because the claimed invention has not been found allowable and the claims as recited in the instant application constitute several inventions in one application. Additionally, if it can be shown that two or more inventions are independent, and there would be serious burden on the examiner if restriction is not required, applicant can be required to restrict the claims presented to one of such independent inventions (see M.P.E.P. 806.06). Furthermore, given that the claims recite such multiple inventions, the search would indeed be unduly extensive and burdensome given that a search group I or II would consist of searching contrasting databases for various references and literature searches.

Thus, the requirement is still deemed proper and is therefore made FINAL.

Claims 25-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d) for foreign priority based on application PCT/EP02/1488 filed in Europe on 12/18/2002, which papers have been placed of record in the file.

IDS

The information disclosure statement filed on June 16, 2005 and September 16, 2005 (specifically items WO 99/55333 and DE 197 37 348) fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the only the information in the abstract of the WO 99/55333 document referred to therein has been considered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 13-14, and 17-18 of copending Application No.11,885,554 in view of Smith et al. (J. Amer. Acad. Derm. 1997, Vol. 39, Iss. 1, pgs. 43-47).

Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a composition comprising sertaconazole or a pharmaceutically acceptable salt.

While the instant application does not include hydrocortisone or antibacterial quinolone compounds or salts or mixtures thereof in the composition, Smith et al. (J. Amer. Derm. 1997, Vol. 39, Iss. 1, pgs. 43-47) discloses the use of the combination of antifungal (i.e. sertaconazole) with corticosteroids (i.e. hydrocortisone) in a composition (see pg. 45, left col. and table 1). Thus, it would have been obvious to one of ordinary skill in the art to add hydrocortisone as disclosed by Smith et al. to the composition of the instant application in order to achieve anti-inflammatory reprieve from skin diseases. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No.11,885,554.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (**see M.P.E.P 608.01 (k)**).

Claims 19-20 are particularly vague and indefinite given that applicant is claiming a composition with a capacity of 4 to 6 ml or 5 ml (**in sentence 1 of both claims**. Given that applicant did not particularly point out if the capacity encompassed in the invention is alluding to the single dose applicator being capable of containing 4 or 5 or 6 ml or whether the capacity is referring to the actual volume of the composition, one of ordinary skill in the art would not be able to fully ascertain the metes and bounds of the aforementioned claims.

As a result of the above inconsistencies, the aforementioned claims are unable to be examined as disclosed given that the scope of the claimed subject matter would not be able to be determined by one of ordinary skill in the art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (**see M.P.E.P 608.01 (k)**).

Claims 21-24 are particularly vague and indefinite given that applicant is claiming a kit comprising the composition of claim 1 and a cream composition containing sertaconazole or one of its pharmaceutically acceptable salts (**in sentence 2)**. Given that applicant did not particularly point out if the kit contains only one composition formulated as a cream or two separate compositions of sertaconazole which includes the composition of claim 1 and a separate cream composition of sertaconazole, one of ordinary skill in the art would not be able to fully ascertain the metes and bounds of the aforementioned claims.

As a result of the above inconsistencies, the aforementioned claims are unable to be examined as disclosed given that the scope of the claimed subject matter would not be able to be determined by one of ordinary skill in the art. However, for the purpose of examination, Examiner will construe that the kit set forth in the claims contains only a cream composition of sertaconazole.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

It is respectfully pointed out that the recitation "vaginal mucoadhesive" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robbie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Foguet et al. (U.S. 5,135,943).

Specifically, Foguet et al. discloses a composition of formula I wherein the sulfur atom is replaced by an oxygen atom and such pharmaceutical composition contain the compound in an amount ranging from 1-5% by weight in a pharmaceutical carrier (see abstract). Particularly, the 1H-imidazole derivative is 1-[2-(7-chloro-3-benzo(b)thenyl)methoxy]-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole (i.e. sertaconazole) and non-toxic salts thereof including mononitrate (see col. 3, lines 10-16). Foguet et al. further demonstrated that sertaconazole possesses high antimycotic activity (see col. 10, lines 10-11) and is available in a 2% cream formulation (col. 12, lines 64-65). Foguet et al. further discloses that these compounds can be formulated as creams, ointments, emulsions, gels in a concentration of 0.1-15% by weight (instant claims 1-2, 5) of the composition (see col. 13, lines 15-35) or for topical composition in a concentration of 0.1-5% (col. 14, lines 10-12). This topical cream (instant claim 3)

composition is further exemplified in example 1 where sertaconazole nitrate (instant claims 1) is an amount of 3 g (i.e. 3%) along with lipophilic excipients such as liquid paraffin (see col. 13, lines 50-58).

Accordingly, the teachings of Foguet et al. anticipate claims 1-5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-24 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Foguet et al. (U.S. 5,135,943).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The Foguet reference is as discussed above and incorporated by reference herein. However, Foguet does not address the composition in a kit.

However, to one of ordinary skill in the art at the time of the invention would have found it obvious to prepare the composition in a kit for marketability purposes.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to add the composition of Foguet et al. in a kit for marketability purposes. Given that Foguet et al. teaches a topical cream composition containing sertaconazole in an amount of 0.1-15% with high antimycotic activity, one of ordinary skill would have been motivated to market such composition in a kit with the reasonable expectation of providing a topical cream composition of sertaconazole to the public that is highly efficient in treating infections.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larnier et al. (U.S. 2004/0101538 A1) in view of Saettone et al. (U.S. 6,423,307 B2).

Larnier et al. teaches a pharmaceutical composition for topical composition comprising an antifungal such as sertaconazole or topically acceptable salts and a second drug together in a topically acceptable carrier (instant claims 1 and 4; see pg. 1, paragraph 0007). Preferred antifungal compounds include sertaconazole (see pg.

1,paragraph 0013). The antifungal component is typically present in an amount of from 0.1-10% (instant claims 1, 2, 5; see pg. 2, paragraph 0029) and can be in the form of emulsion gels, creams or ointments (instant claims 1 and 3) and useful for the prevention or treatment of fungal infections (see pg. 2, paragraphs 0032-0033). Acceptable oils in the composition include liquid paraffin (i.e. lipophilic excipients) in an amount ranging from 2-40% (instant claims 8-9). Conventional excipients can further be added especially preservatives (see pg. 4, paragraph 0047) and thickeners such as the mucoadhesive excipient carbomer (i.e. polyacrylic acid derivatives) and known commercially under the tradename carbopol or carbopol 974, 980, or 1342 (i.e. all polymers of acrylic acid crosslinked with allyl ethers of pentaerythritol; see pg. 3, paragraph 0045). Larnier et al. particularly exemplify the use of mucoadhesive excipients in his emulsion-gels (instant claim 1; gel) such as carbopol 974 P in an amount of 1.0% or 1.4 % in his formulation (instant claim 12; see pg. 4-5, examples 2-4 and 7).

Larnier et al. does not teach the particular nitrate salt of sertaconazole or the instantly claimed preservatives in his composition. Larnier et al. also does not teach mixtures of polyacrylic acid crosslinked with divinyl glycol and carbopol.

Saettone et al. teaches mucoadhesive antimicrobial complexes of polycarbophil (i.e. crosslinked polyacrylic acid with bioadhesive properties and an imidazole derivative with antifungal activity for use as sustained release antifugals for vaginal administration

(see abstract). Saettone teaches the use of imidazole nitrate such as econazole nitrate in his composition in bioadhesive systems (see col. 2, lines 48-55 and see pg. 5, lines 23-27). A number of bioadhesive polymers may be added in such composition including gelatin, cellulose derivatives and polyacrylic acids (instant claims 10-11; see col. 3, lines 58-66) especially polycarbophil (a.k.a. Noveon AA-1; acrylic acid crosslinked with divinyl glycol) which possesses excellent mucoadhesive properties (instant claim 12; see col. 4, lines 1-8 and 22-26). Saettone et al. further suggests the use of polycarbophil with azole antifungal drugs for vaginal topical use (see col. 4, lines 63-67). Saettone et al. also suggests the use of excess polycardophil in order to increase bioadhesivity of the product (see col. 6, lines 40-45). Importantly, Saettone tested several mucoadhesive excipients or bioadhesive polymers and determined that both carbopol 940 (also a polymer of acrylic acid crosslinked with allyl ethers of pentaeryhritol) and polycarbophil showed strong mucoadhesion than other polymers (see col. 9, lines 10-25). Saettone et al. also teaches the use of methyl paraben and propyl paraben at 0.2% and 0.02% in the antifungal composition (see col. 7, formulations 1-5).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to add the aforementioned preservatives of Saettone et al. into the composition of Larnier et al. since Saettone et al. teaches their use in antifungal compositions. Moreover, one of ordinary skill at the time of the invention would have found it obvious to add polycarbophil to the composition of Larnier et al. since Saettone et al. teaches that its addition in antifungal composition increases the mucoadhesivity of

such composition. Given that Larnier et al. teaches a pharmaceutical composition comprising an antifungal such as sertaconazole or its salt with lipophilic excipients, mucoadhesive excipients such as carbopol and antimicrobial preservatives, and Saettone et al. teaches that antifungal compositions can add excess strong mucoadhesive excipients such as polycarbophil, preservatives such as methyl paraben, propyl paraben, one of ordinary skill would have been motivated to add the preservatives of Saettone et al. along with polycarbophil into the composition of Larnier et al. in light of the disclosure of Saettone et al. with the reasonable expectation of providing a gel like topical composition that is highly mucoadhesive and long lasting and efficient in inhibiting fungal growth.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foguet et al. (U.S. 5,135,943) as applied to claims 1-5 and in further view of Jones (U.S. 2,847,011).

The Foguet reference is as discussed above and incorporated by reference herein. However, Foguet does not address the composition as being packed in a single-dose applicator.

Jones teaches that pharmaceutical formulation that can contain liquid, semi-liquid or gels or those adapted for administration into the vagina and packed in a single dose applicator (instant claim 18; see col. 1, lines 15-19). Jones further teaches that such

applicator can neatly and quickly dispensed the composition into the body cavity and discarded after use and is economical (see col. 1, lines 52).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to apply the composition of Foguet et al. into a single dose applicator as taught by Jones since such composition can be quickly and neatly dispensed into a body cavity. Given that Foguet et al. teaches a topical cream composition containing sertaconazole in an amount of 0.1-15% with high antimycotic activity, and Jones teaches the use of a single use applicator for pharmaceutical composition which can quickly and neatly dispense the composition into a body cavity, one of ordinary skill would have been motivated to apply the composition of Fouget et al. into a single dose application as taught by Jones with the reasonable expectation of providing a topical composition that is efficient in its antimycotic activity and a composition that can be easily administered.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L./

Examiner, Art Unit 1617

04/10/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617